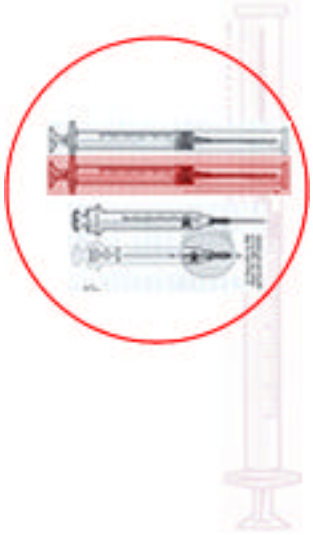
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.



Phase 4: Evaluate Safer Medical Device(s)

For the past seventy-five years, our faith-based heath-care facility has played a critical role in contributing to the quality of life of the 600,000 culturally diversified residents in our community. We are dedicated to carrying out our mission of contributing to healthy communities and promoting quality healthcare to all with compassion. This is accomplished through a full spectrum of diagnostic, therapeutic, preventative, and rehabilitation services, which include Neighborhood Affiliate Physician Offices, Parish Nursing Program and a Health Connection Medical Call Center.

Once the health care facility has identified and screened eligible safer medical devices and decided which device or devices to pilot test in their workplace, the evaluation phase begins. While conducting the device evaluation, NIOSH recommends, and OSHA requires, that health care facilities ensure that participants represent the scope of eventual product users. The following steps will contribute to a successful product evaluation:

- Train health care worker in the correct use of the new device.
- Establish clear criteria and measures to evaluate the device with regard to both health care worker safety and patient care.
- Conduct onsite follow-up to obtain informal feedback, identify problems and provide additional guidance.

1. Describe the *safer medical device evaluated in your facility by providing the following information:*
   a. Device type
      The safety device to be evaluated would be added to the currently used safety-butterfly blood collection set and blood culture bottle to provide protection for the anterior needle.

   b. Department or location in which the device was evaluated
      Once a product has committee approval for trial our Phlebotomy Technical Specialist (PTS) conducts an initial evaluation consisting of ease of use, appropriateness for its specific function, and education required for implementation. This is reported back to the committee before a full trial is conducted.

      This evaluation is presented to the committee, who then decide which departments will be utilizing the product, the most. Blood culture statistical data was used to determine where the highest volume of blood cultures was collected in our facility.

   c. Which staff used the device?
      Blood cultures in our facility are collected primarily by our patient care technicians. Therefore, they would comprise the staff members conducting the new device trial.

2. Describe the staff training on the device.

The manufacturer's representative provided initial training for the new safety device to the PTS. Training of patient care technicians who would conduct the trial was again provided by the manufacturer's representative and the PTS. Visual aids, in the form of posters, demonstrating the proper usage of the device were also available for reference when and if needed.

3. Describe the process used to evaluate the device and the timeframe for this process.

The committee decided that the trial would be conducted in the area demonstrating the highest blood culture collection volume for one month or a minimum of ten blood culture draws per patient care technician. This would allow for sufficient use of the product once they felt comfortable with it to determine its effectiveness.

4. Describe the criteria and measures used in the device evaluation and how it was collected and analyzed.

The patient care technicians performing the trial completed written evaluations. Criteria included in the evaluation process were:

- ease of use
- reliability of product to function as intended
- ability to convert from blood culture collection to vacutainer tube
- disposal of device

Evaluation items were tallied and a summary was presented to committee for review along with any written or personal comments from the trial members.

5. Did the evaluation process that you used give you sufficient information (data) to be able to determine the effectiveness of the device and whether to continue or discontinue its use?

Yes, the criteria included in the evaluation identified the critical aspects that would be affected by implementing the new device.

6. Did you determine whether or not the device was being used as planned during this phase? If so, how? What problems, if any, did you have in getting employees to use the device? How did you resolve those problems?

The trial process was conducted by a controlled group of patient care technicians under the direction of the PTS and no problems were encountered related to appropriate implementation of the new device. The initial education impressed upon them the role the device would play in protecting them from needle stick injuries.

This was proven as a key factor throughout the trial and implementation process that the staff must be made aware of the benefits in using such a device.

7. What lessons were learned during the process of evaluating safer medical devices/ describe the difficulties encountered and how problems were resolved?

   Once the product was selected for trial it was discovered that the size of the device could not be accommodated by the existing sharps containers for disposal. Ironically, the manufacturer of the sharps container was the same as that of the device. The trial process was delayed until the disposal problem was corrected. The manufacturer modified the device so that it would fit safely into the sharps container opening.

8. What would you do differently if you were to begin this process again?

   As mentioned above, be sure that there is a safe accessible means of discarding the used safety device before proceeding with a trial evaluation. Trial members may become disheartened and reluctant to continue if they loose confidence in clarity of the trial process.

9. What advice would you offer a similar facility that is just starting this process?

   Be sure to do a thorough evaluation of all aspects of the new product usage and disposal in your facility.

10. What role did the sharps injury prevention team play in this process?

    Our sharps safety committee is the driving force in any new product evaluation. They conduct a product search, identify possible options for review, define the criteria for evaluation, determine parameters for implementing the trial, and assess the data and feedback from trial users.

11. Please provide any other information you wish to share about the process used or problems encountered in evaluating safer medical devices.

    Most manufacturers of safety devices have evaluation forms for their products. These forms can easily be adapted to include any organization specific criteria or information. Product representatives may be able to supply a reference listing of other institutions using or evaluating the product. This can provide insight regarding any pitfalls that might have occurred.

Materials

Materials distributed at the meeting included a) previous meeting minutes for approval, b) an agenda of items to be discussed - both old and new business, c) copies of

Employee Health Service sharps injury statistics, and d) inventory listing of current sharps supplies stocked in Central Service.

Staff Hours

Type of Staff	Hours Spent on Phase 4
Management	24
Administrative	2
Front-line	32
Total	58

Other, non-labor items

Item
1) Tablet for recording minutes
2) Copy Paper
3) Evaluation Forms
4) Sample product from vendor to conduct trial